# **Complete Summary**

## **GUIDELINE TITLE**

The primary care management of erectile dysfunction.

# BIBLIOGRAPHIC SOURCE(S)

The primary care management of erectile dysfunction. Washington (DC): Department of Veterans Affairs (U.S.); 1999 Jun. 67 p. [86 references]

# **COMPLETE SUMMARY CONTENT**

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

# SCOPE

# DISEASE/CONDITION(S)

IDENTIFYING INFORMATION AND AVAILABILITY

Erectile dysfunction

## **GUIDELINE CATEGORY**

Diagnosis Evaluation Management Treatment

# CLINICAL SPECIALTY

Endocrinology Internal Medicine Urology

**INTENDED USERS** 

Advanced Practice Nurses Physician Assistants Physicians

## GUIDELINE OBJECTIVE(S)

- To present evidence-based guidelines on the management of erectile dysfunction
- To assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing
- To present guidelines to serve as a basis for monitoring local, regional and national patterns of pharmacological care

## TARGET POPULATION

Veterans with erectile dysfunction

## INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Diagnosis of Erectile Dysfunction

- Medical history and physical examination to identify etiologies and comorbidities
  - Sexual, medical, and psychosocial history
  - Assessment of possible risk factors for erectile dysfunction and medical conditions associated with erectile dysfunction (e.g., medications, recreational drug use, atherosclerotic peripheral or cardiovascular disease, prior surgeries or trauma, neurologic illness, endocrinologic illness, psychiatric illness)
  - Focused physical exam emphasizing the genito-urinary, vascular and neurologic systems
- 2. Cardiovascular and ophthalmologic evaluation, with particular attention in considering patients for sildenafil therapy
- 3. International Index of Erectile Function (assessment tool)
- 4. Laboratory evaluation to uncover associated medical conditions and identify treatable causes of erectile dysfunction
  - Testosterone levels
  - Laboratory evaluation for diabetes (fasting plasma glucose)
  - Laboratory evaluation for thyroid disease (thyroid stimulating hormone)
  - Laboratory evaluation for vascular disease (cholesterol levels or lipid profile)
  - Laboratory evaluation of other medical comorbidities (as indicated by history and physical examination)
- 5. Refer to specialists as indicated for further evaluation
  - Sex therapist or mental health professional
  - Endocrinologist
  - Urologist

Treatment/Management

- 1. Health education of patient and partner
  - Information on the causes
  - Risk factors
  - Misconceptions about erectile dysfunction
  - Treatments available and their associated benefits and risks
- 2. Referral to programs as indicated for treatment of lifestyle factors contributing to erectile dysfunction
  - Alcohol or drug abuse programs
  - Smoking cessation programs
- 3. Psychological counseling/sex therapy
- 4. Mechanical devices
  - Vacuum erection devices
  - Constriction devices
- 5. Pharmacological treatment
  - Oral therapy (sildenafil or yohimbine)
  - Urethral suppositories (MUSE)
  - Intracavernosal injections (alprostadil, papaverine, multiple drug)
  - Topical medications
- 6. Surgical interventions
  - Penile prosthesis
  - Penile reconstruction for anatomic abnormalities
  - Vascular reconstruction
- 7. Discussion of treatment options, advantages, disadvantages with partner/spouse to assist in decision making
- 8. Ophthalmic evaluation of patients treated with sildenafil

## MAJOR OUTCOMES CONSIDERED

- Patient satisfaction
- Efficacy of treatment

# METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

# DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature searches were conducted (e.g., Medline, NIH, etc.) with additional peer reviewed literature obtained by members according to their specialty.

# NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The references articles have been assigned a grade of evidence rating, which is based on the Agency for Health Care Research and Quality (AHRQ) guideline development.

## Level of Evidence Grading

- A. Large randomized controlled trails with clear-cut results (low risk or error). Level I
- B. Small, randomized trials with uncertain results (moderate to high risk of error). Level 2
- C. Nonrandomized, contemporaneous controls; nonrandomized, historical and expert opinions; uncontrolled studies, case series, expert opinions and panel consensus. Levels 3, 4, 5

## METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A group of clinical experts in the area of erectile dysfunction (ED) was convened to develop the ED guidelines. The Erectile Dysfunction Committee consisted of healthcare professionals from a variety of sub-specialties including: urology, endocrinology, ophthalmology, internal medicine, spinal cord injury, cardiology, psychology, medical/ethical specialist, nursing, physician assistance and pharmacy. The committee met with weekly teleconferences to discuss the literature and various issues.

Literature searches were conducted (e.g. Medline, NIH, etc.) with additional peer reviewed literature obtained by members according to their specialty. The general algorithm was developed first, followed with the specialty areas. Each specialist led his or her particular area of expertise. The committee worked in concert writing and reviewing the different annotations. If there were questions regarding any aspect of the guidelines, a literature search was rerun, information reevaluated and this process repeated until consensus was obtained. The level of evidence and strength of recommendations were reviewed for each annotation, discussed and graded as a committee.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The references articles have been assigned a strength of recommendation rating, which is based on the Agency for Health Care Research and Quality (AHRQ) quideline development.

# Strength of Recommendation

- I. Usually indicated, always acceptable, and considered useful and effective.
- II a. Acceptable, of uncertain efficacy, and may be controversial. Weight of evidence is in favor of usefulness/efficacy.
- IIb. Acceptable, of uncertain efficacy and may be controversial. May be helpful, not likely to be harmful.
- III. Not acceptable, of uncertain efficacy and may be harmful. Does not appear in the guidelines.

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Peer Review

# DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Draft documents are sent to the field for comments prior to being finalized.

# RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

The recommendations for the primary care management of erectile dysfunction are organized into 7 major algorithms. The algorithms, the objectives and summary/annotations that accompany them, and the evidence supporting the recommendations are presented below. The strength of recommendation grading (I-III) and level of evidence grading (A-C) are defined at the end of the "Major Recommendations" field.

## General Algorithm

Medical History and Physical Exam to Confirm Erectile Dysfunction (ED). Patient Education.

Objective

Describe the critical elements of the history and physical exam, which will assist a provider in evaluating a patient with erectile dysfunction (ED). Describe the importance of patient education.

## Summary

Identification of the etiology of a patient's erectile dysfunction is critically dependent on the history and physical exam. An essential first step is a thorough sexual, medical and psychosocial history. A focused physical exam emphasizing the genito-urinary, vascular and neurologic systems follows and complements the history. Greater emphasis should be placed on examining systems in which symptoms or complaints were elicited during the history. Finding from the history and physical examination may provide a diagnosis or aid in selecting further testing/evaluation.

#### Evidence

History and physical examination is an essential first step in the evaluation of erectile dysfunction. Strength of Recommendation: I; Level of Evidence: C (Process of Care Panel, University of Medicine and Dentistry of New Jersey (UMDNJ), 1998; Korenman, 1998; Sadovsky, Dunn, & Grobe, 1999)

# General Algorithm

# Module A: Laboratory Evaluation of Erectile Dysfunction

# Objective

To describe a rational approach to the laboratory evaluation of erectile dysfunction.

# Summary

Erectile dysfunction (ED) may be related to undiagnosed medical disorders that if treated, may improve the patient's erectile dysfunction. Some patients presenting with erectile dysfunction may not have previously sought medical attention, and thus evaluation of erectile dysfunction offers an opportunity to diagnose and treat associated medical conditions. A rational approach is to do a laboratory evaluation that uncovers associated medical conditions and identifies treatable causes of erectile dysfunction.

Unfortunately, there is only limited evidence to recommend any specific laboratory panel to evaluate erectile dysfunction. Published suggestions vary from a minimal work up, to a moderate work-up, to an extensive laboratory evaluation. For example, the National Institute of Health (NIH) Consensus Conference on Impotence recommends a moderate work up with measurement of testosterone in all patients, and serum prolactin, complete blood count, urinalysis, creatinine, fasting lipid profile, fasting blood sugar, and thyroid function testing in many patients.

In the absence of definitive evidence, selection of laboratory tests for the evaluation of erectile dysfunction can be based on the history, review of symptoms, and physical examination. The goal of selected laboratory testing is to identify important co-morbidities that warrant further evaluation or treatment, as well as help in the identification of the etiology and potential treatment for erectile dysfunction.

#### Evidence

Testosterone in men 50 years of age or older, decreased libido, or abnormal. Strength of recommendation: IIa; Level of evidence: B (Buvat & Lemaire, 1997; Govier, McClure, & Kramer-Levien, 1996).

Fasting blood sugar in patients without history or diagnosis diabetes mellitus. Strength of recommendation: IIa; Level of evidence: C (Korenman, 1998; National Institutes of Health [NIH] Consensus Development Panel conference, 1993).

Thyroid stimulating hormone for symptoms, suspicion of thyroid disease. Strength of recommendation: IIa; Level of evidence: C (Korenman, 1998; NIH Consensus Development Panel conference, 1993).

Screening cholesterol. Strength of recommendation: IIa; Level of evidence: C (Korenman, 1998; NIH Consensus Development Panel conference, 1993).

#### General Algorithm

Module B: Medications

## Objective

To identify medications which may contribute to a patient's erectile dysfunction.

#### Summary

Medications may be important contributors to erectile dysfunction. More than one drug may affect sexual functioning, or medications may be additive to other causes of erectile dysfunction. There may be a temporal relationship between onset of erectile dysfunction and institution of a new medication.

Note: A table listing the medications with potential effects on erectile dysfunction is presented in the original guideline document.

#### Evidence

Consider substitution of selective serotonin reuptake inhibitor (SSRI) with bupropion, nefazodone, or mirtazapine. Strength of recommendation: IIa; Level of evidence: C (Drugs for Depression and Anxiety, 1999; Rosen, Lane & Menza, 1999).

Consider bupropion "augmentation" if not possible to remove/substitute or reduce dose of SSRI. Strength of recommendation: IIa; Level of evidence: B (Ashton & Rosen, 1998).

Consider alpha blockers, angiotensi-converting enzyme (ACE) inhibitors, or calcium channel blockers as alternative antihypertensive treatment. Strength of recommendation: IIa; Level of evidence: C (Drugs That Cause Sexual Dysfunction: An Update, 1992; Brock & Lue, 1993; The Process of Care Model for the Evaluation and Treatment of Erectile Dysfunction, 1998; Glina, 1987).

Assess for impaired ejaculation or anorgasmia. Strength of recommendation: I; Level of evidence: C (Rosen, Lane & Menza, 1999).

# General Algorithm

Module C: Psychology

# Objective

To describe the process of evaluating and treating psychological factors associated with erectile dysfunction and clarify when a referral to a sex therapist or appropriate mental health professional is indicated related to these risk factors.

## Summary

The patient may be referred for sex therapy assessment when there is concern the patient is clinically depressed, has a sexual trauma history, experiences anxiety and/or guilt regarding sex or reports conflict with their partner. Findings from further evaluation of these risk factors may lead to an array of psychosexual interventions designed to achieve symptom relief and allow the patient to enjoy their optimal level of sexual health. It is important to note that erectile dysfunction typically has a multicausal basis and that concurrent, brief sex therapy may be beneficial to patients employing medical treatments for their erectile dysfunction.

#### Evidence

Patients with erectile dysfunction and naturally occurring erections (a.m. or masturbation) are referred for sex therapy. Strength of Recommendation: I; Level of Evidence: C (American Association of Clinical Endocrinologists (AACE), 1998; NIH Consenus Development Panel on Impotence, 1993).

Patients without an organic-based erectile dysfunction but with depression, guilt, anxiety, sexual abuse history or high relationship conflict are referred for sex therapy. Strength of Recommendation: I; Level of Evidence: C (Process of Care Panel, [UMDNJ], 1998); B (Masters, Johnson & Kolodny, 1995).

# General Algorithm

Module D: Endocrinology

# Objective

To describe the endocrine etiologies and evaluation in patients with erectile dysfunction.

# Summary

The two most common endocrine etiologies for erectile dysfunction are testosterone deficiency and diabetes mellitus. In patients with erectile dysfunction and decreased libido a free or unbound testosterone should be obtained. If this is abnormal (see discussion for this section in the original document) the patient should be referred to endocrinology for confirmation of the diagnosis of hypogonadism and for evaluation of the etiology. Other endocrine disorders only rarely present with a principal complaint of erectile dysfunction. Thus other endocrine tests are not warranted without specific symptoms and signs of specific endocrine disorders.

#### Evidence

Measurement of free testosterone. Strength of Recommendation: IIa; Level of Evidence: C (Korenman, 1998; AACE clinical practice guidelines for the evaluation and treatment of male sexual dysfunction, 1998).

Age adjustment of free testosterone. Strength of Recommendation: IIb; Level of Evidence: C (Korenman, 1998; AACE clinical practice guidelines for the evaluation and treatment of male sexual dysfunction, 1998).

Erectile dysfunction virtually never the presenting symptom of diabetes mellitus. Strength of Recommendation: I; Level of Evidence: C (Korenman, 1998; AACE clinical practice guidelines for the evaluation and treatment of male sexual dysfunction, 1998; Jaspan & Green, 3rd ed).

Other endocrine tests not necessary. Strength of Recommendation: I; Level of Evidence: C (Korenman, 1998; AACE clinical practice guidelines for the evaluation and treatment of male sexual dysfunction, 1998).

# General Algorithm

# Module E: Lifestyle

#### Objective

To describe the process of evaluating and treating lifestyle factors associated with erectile dysfunction and clarify when a referral is indicated related to these risk factors.

#### Summary

The patient may be referred for specialty assessment and treatment when there is concern the patient has an addiction to alcohol, tobacco or illegal drugs, which have adverse effects on erectile functioning. All patients who are smoking should

be referred to a smoking cessation program if cessation efforts fail in the primary care setting. Patients with addictions to alcohol and/or drugs should be referred for further assessment and treatment by a polysubstance abuse program. It is important to note that erectile dysfunction typically has a multicausal basis and concurrent combination of therapies may improve treatment outcome.

#### Evidence

Patients who use and have dependence upon alcohol, tobacco or illegal drugs (amphetamines, cocaine, heroin, marijuana, morphine, steroids) should stop their use of these substances via counseling from their doctor and/or participate in a specialized treatment program. Strength of Recommendation: I; Level of Evidence: C (NIH Consensus Development Panel on Impotence NIH Consensus Conference on Impotence, 1993; Kaplan, 1986; Process of Care Panel, [UMDNJ], 1998).

## General Algorithm

# Module F: Neurology/Spinal Cord Injury

# Objective

To describe the evaluation and the treatment of patients with erectile dysfunction due to spinal cord injury and other neurologic conditions.

# Summary

Spinal cord injury (SCI) persons usually have a reflex erection particularly when physically stimulated. This is possible in all supraconal (above S2, 3, 4) lesions. Lesions of the conus and/or cauda equine result in lack or absence of erection on physical stimulation. In addition to spinal cord lesions, a wide variety of diseases of the Central and Peripheral Nervous System can result in erectile dysfunction. Hence a careful neurologic exam is necessary to exclude or identify such illnesses. Neurourologic examination and urodynamics can help diagnose neurologic deficit which will impair bladder function and associated erectile dysfunction. In a recent randomized pilot study of 27 patients with below T5-6 lesion, 65% of the subjects had erections with improved rigidity at the base of the penis with sildenafil. However, responses to the end of treatment questionnaire, indicated that there were no significant differences between the placebo group and the sildenafil group with respect to frequency of erections hard enough for sexual intercourse. The patients with lesions above T5-6 are prone to autonomic dysreflexia. This being a life-threatening situation with sudden rise in blood pressure, they may be given nitrites for emergency management of hypertension and are therefore at risk with sildenafil for severe hypotension. It is important to appreciate that the usual systolic blood pressure of quadriplegics and high tetraplegics may be below 100 mmHg. Other options for the management of erectile dysfunction in these patients include penile implants preferably "semi rigid" which can also help to hold external condom drainage more easily in obese patients with small retractile penis. Other options include vacuum pump devices, intraurethral insertion of alprostadil (MUSE), and intracavernous injections of prostaglandins to manage erectile dysfunction.

#### Evidence

Sildenafil 50 mg (Patient below T5-T6 lesions). Strength of Recommendation: IIb; Level of Evidence: B (Maytom et al., 1999).

Autonomic dysreflexia. Strength of Recommendation: I; Level of Evidence: C (Guttmann & Whitteridge, 1947; Perkash, 1997).

Penile implants. Strength of Recommendation: IIa; Level of Evidence: C (Gould et al., 1992).

# General Algorithm

Penile Disease Present? Refer to Urology

# Objectives

To guide primary care providers (PCP) in the appropriate referral of erectile patients for urological consultation.

# Summary

- Distinction between urological and non-urological causes of erectile dysfunction should be established by primary care providers for the appropriate management decision and referral for urological consultation.
- Significant numbers of patients with erectile dysfunction have non-urological etiologies and can be managed by primary care providers and specialties other than urology. Patients should receive education on the various treatment options for erectile dysfunction; primary care providers can provide initial therapeutic choices such as vacuum erection device or oral medication.
- When there is a lack of a successful response to initial therapy and/or presence of certain urological conditions (discussed below), urology referral is the appropriate next step.

## General Algorithm

# <u>Treatment</u>

## General Principals of Therapy

Secondary causes of erectile dysfunction should be eliminated prior to instituting other therapies wherever possible. Since erectile dysfunction is frequently multifactorial, correcting some etiologies may not resolve the erectile dysfunction. Furthermore; some secondary causes may not be correctable (i.e., it may not be possible to use an alternative medication). The various treatment options and their advantages/disadvantages should then be discussed with the patient and partner/spouse. Of the total available treatments the following two are most appropriate initial therapies to be prescribed by primary care physicians (e.g., vacuum device, sildenafil).

See treatment table presented in the original guideline document.

# Module G-a: Vacuum Therapy

Vacuum Pump Therapy for Erectile Dysfunction

# Objective

To describe the process of evaluating and treating erectile dysfunction with vacuum pump therapy.

# Summary

A non-pharmacological/non-surgical approach in the treatment of erectile dysfunction should always be considered as a first-line treatment modality. Vacuum pump therapy has no drug interactions and side effects are minimal. The occurrence of erectile dysfunction associated with such co-morbidities such as diabetes, hypertension, atherosclerosis, autonomic neuropathy, drug effects, hypogonadism, and other major medical problems lends the potential for drugdrug interactions when a pharmacological approach is used for treatment.

Multiple studies have been done over the last several years, which clearly document the effectiveness of a vacuum tumescence device in varied groups of patients. Patient satisfaction with motivated subjects and partners is substantial.

The successful utilization of a vacuum tumescence device depends on appropriate patient education and counseling. Compliance and acceptance of therapy have been shown to be dependent on individualized instruction, return demonstration, and evaluation of decreased effectiveness with re-education by a fully trained, qualified instructor in a private setting. Qualified instructors may include urologists, physician extenders, nurse specialists, or certified manufacturer representatives. Patient education may also include the sexual partner to help increase successful utilization and satisfaction with the device. The use of written materials, videotapes (available from the supplier), and self-demonstrations are extremely valuable in achieving adequate patient education with the use of the device. Most patient dissatisfaction results from inadequate education and training in the use of the vacuum device. The utilization of certified representatives from the supplier of the product provides a cost-efficient method of providing patient education without requiring the use of clinic staff/personnel, while enhancing patient compliance with therapy and should be given priority of consideration.

### Evidence

First line therapy. Strength of recommendation: I; Level of evidence: C (Korenman et al., 1990).

Patient education. Strength of recommendation: I; Level of evidence: C (Gould et al., 1992).

# Module G-b: Pharmacologic/Sildenafil

## Objectives

- To describe the indications, efficacy and satisfaction, and treatment protocol including dose escalation.
- To characterize the absolute contraindications and the relative contraindications and other clinical conditions including concurrent medication administrations where sildenafil must be used with caution.
- To review other adverse effects of sildenafil.

Annotation (a): Patient has a contraindication to sildenafil use.

## Objective

To describe the indications, efficacy and satisfaction, and treatment protocol including dose titration.

# Summary

Sildenafil is one of two initial therapies for erectile dysfunction available to primary care physicians. It is appropriate where there are no absolute contraindications and should be used with caution in some patients with relative contraindications (see Objective (b) below). It may be considered first line therapy (along with use of the vacuum pump) after secondary etiologies of erectile dysfunction have been considered and eliminated when this is clinically reasonable. In patients at higher risk of adverse events the starting dose of sildenafil should be low, (25 mg) and the evaluation interval earlier and more frequent than those patients at low risk. In patients at higher risk for adverse events (see Table 1 of the original guideline document) without an absolute contraindication for sildenafil and who desire therapy then sildenafil should be started at the lowest dose (25 mg). The first dose may be given in the clinic and the vital signs monitored in the clinic. Initial prescription fills should give only limited supplies of sildenafil. These individuals should be reevaluated early and frequently and only slowly titrated up to the maximum 100 mg dose (or 50 mg dose in those using medications which raise serum concentrations of sildenafil see above). In patients at low risk for adverse events, the starting dose can be 50 mg. However, the initial prescription should still be limited and the patient reevaluated for efficacy and adverse events. Based on information from other healthcare plans, the manufacturer of sildenafil and from sexual behavior studies, the number of tablets (of the effective dose) commonly prescribed ranges from 3 to 6 tablets per patient, per month. The manufacturer has provided prescription dispensing data, which shows the number of tablets prescribed per patient per month, is currently at four. VA practitioners may want to use the range as a reference point when prescribing sildenafil.

Annotation (b): Patient with potential risk to sildenafil use.

## Objective

To characterize the absolute contraindications and the relative contraindications and other clinical conditions including concurrent medication administrations where sildenafil must be used with caution.

# Summary

Sildenafil is absolutely contraindicated in patients using prescribed or recreational organic nitrates (see Table 2 of the original guideline document) and in patients with known hypersensitivity to sildenafil. In addition, sildenafil is relatively contraindicated and should be used with caution in a number of additional circumstances including clinical conditions associated with low blood pressure, administration of medications and chronic renal and hepatic diseases which may increase the serum concentrations or prolong the presence in serum of sildenafil. It does not appear that sildenafil directly affects the heart. However, the use of sildenafil in patients with cardiac disease who are not currently taking nitrates is controversial and warrants substantial caution.

Annotation (c): Adverse drug event.

Objective

To review other adverse effects of sildenafil.

Summary

The major adverse effects of sildenafil are related to vasodilation. The most significant of those effects is hypotension discussed above but also includes headache, flushing and nasal congestion. (See Table 4 of the original document).

The International Index of Erectile Function (IIEF) in the Assessment of Erectile Dysfunction

Objective

To described the International Index of Erectile Function and its role in the assessment and diagnosis of erectile dysfunction.

Summary

The International Index of Erectile Function is a 15 item, self-administered scale useful as one evaluation strategy in a comprehensive assessment of erectile dysfunction. The scale has been normed cross-culturally, is psychometrically sound with high reliability and validity, and demonstrates sensitivity and specificity for detecting changes in erectile functioning in patients with erectile dysfunction

Evidence

Inclusion of International Index of Erectile Function (IIEF) or equivalent as assessment measure during initial of erectile dysfunction and as measure treatment progress. Strength of recommendation: I; Level of evidence: C (Process of Care Panel, [UMDNJ], 1998), B (Rosen et al., 1996), A (Goldstein et al., 1998).

Level of Evidence Grading

- A. Large randomized controlled trails with clear-cut results (low risk or error). Level I
- B. Small, randomized trials with uncertain results (moderate to high risk of error). Level 2
- C. Nonrandomized, contemporaneous controls; nonrandomized, historical and expert opinions; uncontrolled studies, case series, expert opinions and panel consensus. Levels 3, 4, 5

## Strength of Recommendation

- I. Usually indicated, always acceptable, and considered useful and effective.
- II a. Acceptable, of uncertain efficacy, and may be controversial. Weight of evidence is in favor of usefulness/efficacy.
- IIb. Acceptable, of uncertain efficacy and may be controversial. May be helpful, not likely to be harmful.
- III. Not acceptable, of uncertain efficacy and may be harmful. Does not appear in the guidelines.

## CLINICAL ALGORITHM(S)

## Algorithms are provided for:

- 1. General Algorithm
- 2. Module A: Laboratory Evaluation of Erectile Dysfunction
- 3. Module D: Endocrinology
- 4. Module E: Lifestyle
- 5. Module F: Neurology/Spinal Cord Injury
- 6. Module G-a: Vacuum Therapy
- 7. Module G-b: Pharmacologic/Sildenafil

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

## REFERENCES SUPPORTING THE RECOMMENDATIONS

## References open in a new window

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

This guideline is based on nationally recognized treatment guidelines, current literature and expert opinion from clinicians across the Veterans Administration system.

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## POTENTIAL BENEFITS

• Appropriate evaluation and management of erectile dysfunction

- Improve the quality of patient care
- Patient satisfaction
- Improved erectile function

#### POTENTIAL HARMS

• Sildenafil. The major adverse effects of sildenafil are related to vasodilation. The most significant of those effects is hypotension but also includes headache, flushing and nasal congestion.

Note: High-risk patients/clinical conditions for adverse side effects with sildenafil are discussed in the original guideline document.

- Vacuum erection devices. If used aggressively, vacuum erection devices can cause some mild bruising initially.
- MUSE. One out of four people get an aching side effect. With some people it is mild, some people it is more intense. There might be some burning urethral pain the first few times it is used.
- Penile injection therapy. Scar tissue formation can occur if the patient does
  not rotate needle sites. Scar tissue formation is more prevalent in injections
  when papaverine is used, not as much of a problem with alprostadil.
  Prolonged erection is the most common side effect with injection treatment. If
  the dose is too high the patient can end up with an erection that lasts four,
  five, six hours. After two hours, it hurts; after four hours the patient begins
  having permanent tissue damage because he does not have blood flowing in
  to the penis to get rid of the waste products from cells. Another side effect is
  bruising.
- Surgery/Penile implants. There is a small risk of infection.
- Yohimbine. Yohimbine (oral therapy) can cause liver toxicity and hypertension; in addition to all of the risks of hormone replace therapy.

# QUALIFYING STATEMENTS

## QUALIFYING STATEMENTS

 Guidelines are not considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the same results. The ultimate judgment regarding the propriety of any course of conduct must be made by the clinician in light of individual patient situations.

# IMPLEMENTATION OF THE GUIDELINE

## DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Getting Better Living with Illness

## IOM DOMAIN

Effectiveness
Patient-centeredness

# IDENTIFYING INFORMATION AND AVAILABILITY

# BIBLIOGRAPHIC SOURCE(S)

The primary care management of erectile dysfunction. Washington (DC): Department of Veterans Affairs (U.S.); 1999 Jun. 67 p. [86 references]

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

# DATE RELEASED

1999 Jun

# GUIDELINE DEVELOPER(S)

Department of Veterans Affairs - Federal Government Agency [U.S.] Veterans Health Administration - Federal Government Agency [U.S.]

# SOURCE(S) OF FUNDING

**United States Government** 

#### **GUI DELI NE COMMITTEE**

- Medical Advisory Panel (MAP) for the Pharmacy Benefits Management Strategic Healthcare Group
- Pharmacy Benefits Management (PBM) Strategic Healthcare Group (SHG)

# COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Medical Advisory Panel (MAP) for the Pharmacy Benefits Management Strategic Healthcare Group: The Medical Advisory Panel (MAP) comprises practicing Veterans Affairs (VA) and Department of Defense physicians from facilities across the nation: Peter Glassman, MBBS, MSc (Chair); Howard R. Bromley, M.D.; Barry Cusack, M.D.; Gregory Dalack, M.D.; Michael Ganz, M.D.; C.B. Good, M.D., M.P.H.; Patricia S. Hlavin, M.D., MS.; Donald Holleman, M.D.; William Korchik, M.D.; John Pope, M.D.; Alexander Shepherd, M.D.

Pharmacy Benefits Management (PBM) Strategic Healthcare Group (SHG): John E. Ogden, R.Ph., M.S., FASHP; Andy Muniz, R.Ph., M.S., FASHP; Michael A.

Valentino, R.Ph., MHSA; Muriel Burk, Pharm.D.; Christine Chandler, Pharm.D.; June T. Cheatham; Fran Cunningham, Pharm.D.; Elaine M. Furmaga, Pharm. D.; Lori J. Golterman, Pharm.D.; Cathy Kelley, Pharm.D.; Deborah Khachikian, Pharm.D.; Suzanne Lenz, R.Ph.; Lisa Torphy; Kathy Tortorice, Pharm.D., BCPS.

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

An update is not in progress at this time.

#### **GUIDELINE AVAILABILITY**

Electronic copies: Available (in PDF format) from the <u>Department of Veterans</u> Affairs Web site.

Print copies: Department of Veterans Affairs, Veterans Health Administration, Office of Quality and Performance (10Q) 810 Vermont Ave. NW, Washington, DC 20420.

## AVAILABILITY OF COMPANION DOCUMENTS

None available

## PATIENT RESOURCES

None available

## NGC STATUS

This summary was completed by ECRI on February 9, 2001. The information was verified by the guideline developer on November 2, 2001.

# **COPYRIGHT STATEMENT**

No copyright restrictions apply.

#### © 1998-2004 National Guideline Clearinghouse

Date Modified: 5/10/2004

# FIRSTGOV

